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मानक

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“The Right to Information, The Right to Live”

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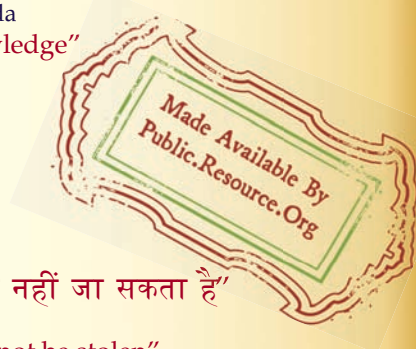
IS 5345 (1996): Sodium Saccharin, Food Grade [FAD 8: Food Additives]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक
सोडियम सेक्रीन, खाद्य ग्रेड — विशिष्टि
(दूसरा पुनरीक्षण)

Indian Standard
SODIUM SACCHARIN, FOOD GRADE —
SPECIFICATION
(*Second Revision*)

ICS 67.220.20

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
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FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Food Additives Sectional Committee had been approved by the Food and Agriculture Division Council.

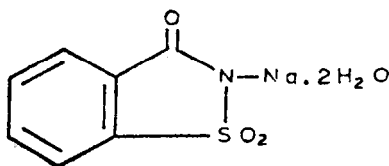
Sodium saccharin is a non-nutritive sweetner. It is taken by diabetics and those who need low calory diet as a substitute for cane sugar. It is about 500 times sweeter than sugar. It is a colourless crystal or white crystalline powder having faint aromatic odour. It is used in specifically notified food products (under PFA Rules) as artificial sweetener within the prescribed limits. This standard is aimed to check the purity. Besides the standard is intended to guide the indegenous manufacturers in making their products conform to specifications that are accepted by scientists, health authorities and international bodies and the consumer industries to use it within the limits prescribed by the health authorities.

This standard was first issued in 1969 and was revised in 1978. It is being revised to make the following changes/additions:

- a) To provide a separate clause for description incorporating the solubility properties to keep the standard in line with the Food Chemical Codex, NRC.
- b) To reduce the limit for toluene sulfonamides.
- c) To substitute the requirement of lead by heavy metals and the corresponding changes in test method.
- d) To include directions for storage and expiry date under the marking clause.

Chemical Names and Formulae

The recognized chemical names are sodium *o*-benzosulfimide; sodium salt of 2, 3-dihydro-3-oxobenzisulfonazole, 1,2-benzisothiazolin-3-one-1, 1-dioxide sodium salt dihydrate. Its common name is soluble saccharin. Empirical formula is $C_7H_4NNaO_3S \cdot 2H_2O$. Its molecular weight is 241.19 and structural formula is as under:



In the preparation of this standard, assistance has been derived from the following publications:

India. Ministry of Health. Pharmacopoeia of India 1966. ED. 2

Food Chemical Codex. Third Edition. National Academy of Sciences, National Research Council, Washington DC, USA.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2:1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

SODIUM SACCHARIN, FOOD GRADE — SPECIFICATION (Second Revision)

1 SCOPE

This standard prescribes the requirements and the methods of sampling and test for sodium saccharin, food grade.

2 REFERENCES

The following Indian Standards are necessary adjuncts to this standard:

IS No.	Title
460	Test sieves :
(Part 1) : 1985	Wire cloth test sieves (<i>third revision</i>)
(Part 2) : 1985	Perforated plate test sieves (<i>third revision</i>)
(Part 3) : 1985	Methods of examination of apertures of test sieves (<i>third revision</i>)
1070 : 1992	Reagent grade water (<i>third revision</i>)
1699 : 1995	Methods of sampling and test for synthetic food colours (<i>second revision</i>)
2362 : 1993	Method for determination of water by the Karl Fischer method (<i>second revision</i>)
5058 : 1996	Sodium citrate, food grade (<i>first revision</i>)

3 DESCRIPTION

3.1 It is white crystals or white crystalline powder. It is odourless or having a faint odour. It is intensely sweet to taste, even in dilute solution. 1 g is soluble in 1.5 ml of water and in about 50 ml of alcohol.

NOTE — The solubility is intended only as information regarding approximate solubility and is not to be considered as a quality requirement and is of minor significance as a means of identification or determination of purity and dependence must be placed on other specifications.

4 REQUIREMENTS

4.1 Identification

4.1.1 Dissolve about 100 mg of the material in 5 ml of 5 percent sodium hydroxide solution. Evaporate to dryness and gently fuse the residue over a small flame until it no longer ammonia evolves. After the residue has cooled, dissolve it in 20 ml of water, neutralize the solution with dilute hydrochloric acid and filter. The addition of a drop of ferric chloride solution (9 g of ferric chloride and sufficient water to make 100 ml) to the filtrate shall produce a violet colour.

4.1.2 Mix 20 mg of the material with 40 mg of the resorcinol, add 10 drops of sulphuric acid and heat the mixture in a liquid bath at 200°C for 3 minutes. After cooling add 10 ml of water and an excess of sodium hydroxide solution (dissolve 4.3 g sodium hydroxide in water and make it to 100 ml). A fluorescent green liquid shall result.

4.1.3 The residue obtained by igniting a 2-g sample shall give positive test for sodium, when tested by the method given in 4.1.3.1.

4.1.3.1 Test for sodium

A solution of a sodium compound, previously converted to chloride or nitrate, when mixed with 5 times its volume of cobalt-uranyl acetate, a golden yellow precipitate is formed on shaking.

Sodium compounds impart an intense yellow colour to a non-luminous flame.

4.1.4 To 10 ml of a 10 percent solution, add 1 ml of hydrochloric acid. Wash the crystalline precipitate of saccharin formed with cold water and dry at 105°C for 2 h. The residue shall melt between 226°C and 230°C.

4.2 The material shall also conform to the requirements given in Table 1.

5 PACKING, STORAGE AND MARKING

5.1 Packing

The material shall be filled in amber colour glass containers or any other containers with as little air space

as possible. The container shall be such as to preclude contamination of the contents with metals or other impurities.

5.2 Storage

The material shall be stored in a cool and dry place so as to avoid excessive exposure to heat.

5.3 Marking

5.3.1 Each container shall be legibly and indelibly marked with the following information:

- Name of the material, including the words 'Food Grade';
- Name and address of the manufacturer;
- Net content, when packed;
- Batch or code number;
- Direction for storage;
- Expiry date; and
- Any other requirements as specified under the *Standards of Weights and Measures (Packaged Commodities) Rules, 1977*

Prevention of Food Adulteration Rules, 1955.

5.3.2 BIS Certification Marking

The product may also be marked with the Standard Mark.

5.3.2.1 The use of the Standard mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

6 SAMPLING

6.1 The representative samples of the material shall be drawn according to the method prescribed in 4 of IS 1699 : 1995.

7 QUALITY OF REAGENTS

Unless specified otherwise, pure chemicals and distilled water (*see* IS 1070:1992) shall be employed in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

Table 1 Requirements for Sodium Saccharin, Food Grade
(Clause 4.2)

Sl No.	Characteristic	Requirement	Method of Test, Ref to	
			Cl No. of Annex A	Other Indian Standards
(1)	(2)	(3)	(4)	(5)
i)	Purity as $C_7H_4NNaO_3S$, after drying at 120°C for 4 h, percent by mass	99 to 101	A-1	—
ii)	Loss on drying, percent by mass, <i>Max</i>	15	A-2	—
iii)	Acidity and alkalinity	To pass the test	A-3	—
iv)	Benzoate and salicylate	do	A-4	—
v)	Readily carbonizable substances	do	A-5	—
vi)	Toluenesulfonamides, mg/kg, <i>Max</i>	25	A-6	—
vii)	Heavy metals (as Pb), mg/kg, <i>Max</i>	10	—	Annex E of IS 5058:1996
viii)	Arsenic (as As), mg/kg, <i>Max</i>	2	—	15 of IS 1699:1985
ix)	Selenium as (Se), mg/kg, <i>Max</i>	30	A-7	—

ANNEX A

(Table 1)

METHODS OF TEST FOR SODIUM SACCHARIN

A-1 PURITY

A-1.0 Two methods have been specified. Any methods may be used depending on the facilities available.

A-1.1 Method 1

A-1.1.1 Procedure

Weigh accurately about 500 mg of the material and transfer it quantitatively to a separator with the aid of 10 ml of water. Add 2 ml of diluted hydrochloric acid, and extract the precipitated saccharin first with 30 ml, then with four 20 ml portions of a solvent composed of 9 volumes of chloroform and 1 volume of alcohol. Filter each extract through a small filter paper moistened with the solvent mixture, and evaporate the combined filtrates on a steam-bath to dryness. Dissolve the residue in 75 ml of hot water, cool, add phenolphthalein and titrate with 0.1 N sodium hydroxide. Each millilitre of 0.1 N sodium hydroxide is equivalent to 20.52 mg of sodium saccharin ($C_7H_4NNaO_3S$).

A-1.2 Method 2

A-1.2.1 Reagents

A-1.2.1.1 Acetic acid — glacial.

A-1.2.1.2 Crystal violet-glacial acetic acid indicator solution

A-1.2.1.3 Perchloric acid — 0.1 N.

A-1.2.2 Procedure

Dissolve about 0.3 g of previously dried sample, accurately weighed, in 20 ml of glacial acetic acid. Add 2 drops of crystal violet-glacial acetic acid indicator, and titrate with 0.1 N perchloric acid. End-point shall be when violet colour of solution change to green *via* blue. Perform a blank determination, and make any necessary correction. Each millilitre of 0.1 N perchloric acid is equivalent to 20.52 mg of sodium saccharin ($C_7H_4NNaO_3S$).

A-2 LOSS ON DRYING

A-2.1 For routine purposes, loss on drying shall be determined by drying the sample at 120° C for 4 hours. In case of dispute it shall be determined as moisture by the Karl Fischer method described in IS 2362 : 1993.

A-3 TEST FOR ACIDITY AND ALKALINITY

A-3.1 Dissolve 1 g of the sample in 10 ml of freshly boiled and cooled water. Add one drop of phenolphthalein indicator. No pink colour shall appear. Add one drop of 0.1 N sodium hydroxide. A pink colour shall appear.

A-4 TEST FOR BENZOATE AND SALICYLATE

A-4.1 To 10 ml of a 5 percent solution, previously acidified with 5 drops of dilute acetic acid, add 3 drops of 9 percent ferric chloride. No precipitate or violet colour shall appear.

A-5 READILY CARBONIZABLE SUBSTANCES

A-5.1 Reagents

A-5.1.1 Sulphuric Acid

A-5.1.2 Matching Fluid

Composed of 0.1 ml of cobalt chloride solution (*see* A-5.1.2.1), 0.4 ml of ferric chloride solution (*see* A-5.1.2.2), 0.1 ml cupric sulphate solution (*see* A-5.1.2.3) and 4.4 ml of water.

A-5.1.2.1 Cobalt chloride solution

Dissolve about 65 g of cobaltous chloride ($CoCl_2 \cdot 6H_2O$) in enough of a mixture of 25 ml of hydrochloric acid and 975 ml of water to make 1 000 ml. Place exactly 5 ml of this solution in a 250-ml iodine flask, add 5 ml of 3 percent hydrogen peroxide and 15 ml of 20 percent sodium hydroxide solution. Boil for 10 minutes, cool, and add 2 g of potassium iodide and 20 ml of 25 percent sulphuric acid. When the precipitate has dissolved, titrate the liberated iodine with 0.1 N sodium thiosulphate solution, adding starch. Each millilitre of 0.1 N sodium thiosulphate is equivalent to 23.8 mg of cobaltous chloride. Adjust the final volume of the solution by adding enough of the mixture of hydrochloric acid and water to make each millilitre contain 59.5 mg of cobaltous chloride.

A-5.1.2.2 Ferric chloride solution

Dissolve about 55 g of ferric chloride ($FeCl_3 \cdot 6H_2O$) in enough of a mixture of 25 ml hydrochloric acid and 975 ml of water to make 1 000 ml. Place 10 ml of this solution in a 250-ml iodine flask, add 15 ml of water and 3 g of

potassium iodide, and allow the mixture to stand for 15 minutes. Dilute with 100 ml of water, and titrate the liberated iodine with 0.1 N sodium thiosulphate solution, adding starch as indicator. Each millilitre of 0.1 N sodium thiosulphate is equivalent to 27.03 mg of ferric chloride. Adjust the final volume of the solution by adding enough of the mixture of hydrochloric acid and water to make each millilitre contain 45.0 mg of ferric chloride.

A-5.1.2.3 Cupric sulphate solution

Dissolve about 65 g of cupric sulphate ($\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$) in enough of a mixture of 25 ml of hydrochloric acid and 975 ml of water to make 1 000 ml. Place 10.0 ml of this solution in a 250-ml iodine flask, add 40 ml of water, 4 ml of acetic acid and 3 g of potassium iodide. Titrate the liberated iodine with 0.1 N sodium thiosulphate solution, adding starch. Each millilitre of 0.1 N sodium thiosulphate is equivalent to 24.97 mg of cupric sulphate. Adjust the final volume of the solution by adding enough of the mixture of hydrochloric acid and water to make each millilitre contain 62.4 mg of cupric sulphate.

A-5.2 Procedure

Dissolve 200 mg of sodium saccharin in 5 ml of sulphuric acid. Keep at 48 to 50°C for 10 minutes. The solution shall not have deeper colour than the matching fluid (see A-5.1.2).

A-6 DETERMINATION OF TOLUENESULFONAMIDES

A-6.0 Two methods have been specified. Any method may be used depending upon the facilities available.

A-6.1 Method 1 — Gas Chromatography

A-6.1.1 Reagents

A-6.1.1.1 Methylene chloride

Use a suitable pure grade, equivalent to the product obtained by distillation in all-glass apparatus.

A-6.1.1.2 Internal standard stock solution

Transfer 100 mg of 95 percent *n*-tricosane into a 10-ml volumetric flask. Dissolve in *n*-heptane, dilute to volume with the same solvent, and mix.

A-6.1.1.3 Stock standard preparation

Transfer 20 mg each of reagent grade *o*-toluenesulfonamide and *p*-toluenesulfonamide into a 10-ml volumetric flask. Dissolve in methylene chloride, dilute to volume with the same solvent, and mix.

A-6.1.1.4 Diluted standard preparation

Pipette into five 10-ml volumetric flasks, 0.1, 0.25, 1.0,

2.5 and 5.0 ml respectively, of the 'stock standard preparation'. Pipette 0.25 ml of the 'internal standard stock solution' into each flask, dilute each to volume with methylene chloride and mix. These solutions contain 250 µg of *n*-tricosane, plus respectively, 20, 50, 200, 500 and 1 000 µg per ml of each toluenesulfonamide, plus 250 mg of *n*-tricosane.

A-6.1.1.5 Test preparation

Dissolve 2.00 g of the sample in 8.0 ml of 5 percent sodium bicarbonate solution. Mix the solution thoroughly with 10.0 g of chromatographic siliceous earth (Celite 545 or equivalent). Transfer the mix into a 25 mm × 250 mm chromatographic tube having a fritted glass disk and a Teflon stopcock at the bottom, and a reservoir at the top. Pack the contents of the tube by tapping the column on a padded surface, and then by tamping firmly from the top. Place 100 ml of methylene chloride in the reservoir and adjust the stopcock so that 50 ml of eluate is collected in 20 to 30 minutes. To the eluate add 25 µl of 'internal standard stock solution'. Mix, and then concentrate the solution to a volume of 1.0 ml in a suitable concentrator tube fitted with a modified Snyder column, by using a Kontes tube heater maintained at 90°C.

A-6.1.2 Procedure

A-6.1.2.1 Inject 2.5 µl of the test preparation (see A-6.1.1.5) into a suitable gas chromatograph equipped with a flame-ionization detector. The column should be of glass, approximately 3 m in length and 2 mm in inside diameter, and packed with 3 percent phenylmethyl silicone on 100- to 120-mesh equivalent to 150 to 125 micron IS test sieve [see IS 460 (Parts 1, 2 and 3)]: 1985 silanized calcined diatomaceous silica. (Caution: The glass column should extend into the injector for on-column injection and into the detector base to avoid contact with metal). The carrier is helium, flowing at a rate of 30 ml per minute. The injection port, column, and detector are maintained at 225°C, 180°C, and 250°C respectively. The instrument attenuation setting should be such that 2.5 µl of the 'diluted standard preparation' containing 200 µg per ml of each toluenesulfonamide gives a response of 40 to 80 percent of full-scale deflection. Record the chromatogram, note the peaks for *o*-toluenesulfonamide, *p*-toluenesulfonamide, and the *n*-tricosane internal standard, and calculate the areas for each peak by suitable means. The retention times for *o*-toluenesulfonamide, *p*-toluenesulfonamide, and *n*-tricosane are about 5, 6 and 15 minutes, respectively.

A-6.1.2.2 In a similar manner, obtain the chromatograms for 2.5 µl portions of each of the five 'diluted standard

preparations', and for each solution determine the areas of the *o*-toluenesulfonamide, *p*-toluenesulfonamide, and *n*-tricosane peaks. From the values thus obtained, prepare standard curves by plotting concentration of each toluenesulfonamide, in μg per ml *versus* the ratio of the respective toluenesulfonamide peak area to that of *n*-tricosane. From the standard curve determine the concentration, in μg per ml, of each toluenesulfonamide in the 'test preparation'. Divide each value by 2 to convert the result to parts per million of toluenesulfonamide in the 2-g sample taken for analysis.

NOTE — If the toluenesulfonamide content of the sample is greater than about 500 parts per million, the impurity may crystallize out of the methylene chloride concentrate (see A-6.1.1.5). Although this level of impurity exceeds that permitted by the specification, the analysis may be completed by diluting the concentrate (usually 1:10 is satisfactory) with methylene chloride containing 250 μg of *n*-tricosane per ml, and by applying appropriate dilution factors in the calculation. Care shall be taken to redissolve completely any crystalline toluenesulfonamide to give a homogeneous solution.

A-6.2 Method 2— Thin Layer Chromatography

A-6.2.1 Apparatus

A-6.2.1.1 Flat glass plates — 200 mm $\times$ 100 mm.

A-6.2.1.2 Micro-pipette

A-6.2.1.3 Developing chamber — lined with filter paper.

A-6.2.2 Reagents

A-6.2.2.1 Silica gel G

A-6.2.2.2 Chloroform

A-6.2.2.3 Methyl alcohol

A-6.2.2.4 Ammonia solution — strong.

A-6.2.2.5 4-sulphamoylbenzoic acid — reference material.

A-6.2.2.6 Toluene-2-sulfonamide acid — reference material.

A-6.2.2.7 Sodium hypochloride solution

Diluted with water to contain 0.5 percent (*m/v*) of available chlorine.

A-6.2.2.8 Potassium iodide

A-6.2.2.9 Starch mucilage

A-6.2.2.10 Glacial acetic acid

A-6.2.2.11 Solution A

4 volumes of methyl alcohol plus 1 volume of acetone

plus 0.5 percent (*m/v*) of the sample.

A-6.2.2.12 Solution B

4 volumes of methyl alcohol plus 1 volume of acetone plus 0.005 percent (*m/v*) of the 4-sulphamoylbenzoic acid.

A-6.2.2.13 Solution C

4 volumes of methyl alcohol plus 1 volume of acetone plus 0.005 percent (*m/v*) of the toluene-2-sulfonamide.

A-6.2.3 Procedure

A-6.2.3.1 Prepare suspension of silical gel G. Spread the suspension on the plates about 0.25 mm thick. Allow to stand until the coating sets and then dry the plates at 105° to 110°C for one hour. Protect the plates from moisture. Pour into the developing chamber sufficient quantity of mobile phase (100 volumes of chloroform + 50 volumes of methyl alcohol + 11.5 volume of strong ammonia solution) to form a layer about 15 mm deep. Close the tank for one hour at 20°C to 27°C. Remove the narrow strips of the coating, about 5 mm inside from the margins of the chromatoplate. Using micro-pipette apply separately to the chromatoplates 2 ml each of solutions A, B and C.

These spots should be about 25 mm from the bottom of the plates and not less than 25 mm from the sides of the plates. The diameter of the spots should not be more than 6 mm. Dry the spots and place the chromatoplates in the developing chamber at 20°C to 27°C until the mobile phase has ascended to the 150 mm line. Remove the plates and dry them in current of warm air. Then heat at 105°C for five minutes. Spray the hot plates with the sodium hypochlorite solution. Dry in a current of cold air until sprayed area of the plate below the line of application give at most a faint blue colour with a drop of a mixture, prepared by dissolving 0.5 percent (*m/v*) of potassium iodide in starch mucilage containing 1 percent (*m/v*) of glacial acetic acid. Avoid prolonged exposure to cold air. Spray the plates with the same mixture. The spots in the chromatograms obtained with solution (B) and (C) should be more intense than any corresponding spots in the chromatogram obtained with solution (A).

A-7 DETERMINATION OF SELENIUM

A-7.1 Reagents

A-7.1.1 Selenium Stock Solution

Transfer 120 mg of metallic selenium (Se) into a 1 000-ml volumetric flask, and 100 ml of dilute nitric acid (1 in 2), warm gently on a steam-bath to effect solution, and dilute to volume with water. Transfer 5 ml of this solution

IS 5345 : 1996

into a 200-ml volumetric flask, dilute to volume with water, and mix. Each millilitre of this solution contain 3 µg of selenium ion (Se).

A-7.1.2 *Standard Selenium Solution*

Just prior to use, transfer 20.0 ml of selenium stock solution (60 µg Se) into a 200 mm × 25 mm test tube, add 20 ml of hydrochloric acid, and mix.

A-7.1.3 *Sample Solution*

Transfer 2 g of the sample to a 250-ml Erlenmeyer flask, and cautiously add 10 ml of 30 percent hydrogen peroxide. After the initial reaction has subsided, add 6 ml of 70 percent perchloric acid, heat slowly until white fumes of perchloric acid are copiously evolved, and continue heating gently for a few minutes to ensure decomposition of any excess peroxide. If the solution is brownish in colour due to nondecomposed organic

matter, add a small portion of the peroxide solution and heat again to white perchloric acid fumes, repeating, if necessary until decomposition of the organic matter shall be complete and a colourless solution is obtained. Cool, add 10 ml of water, and filter into a 200 mm × 25 mm test tube. Wash the filter paper with hot water until the filtrate measures 20 ml, add 20 ml of hydrochloric acid and mix.

A-7.2 **Procedure**

Place the test tubes containing the standard selenium solution and the sample solution in a water-bath, and heat until the temperature of the solution reaches 40°C. To each tube, add 400 mg of ascorbic acid stir until dissolved and maintain at 40°C for 30 minutes. Cool the solution, dilute with water to 50 ml and mix. Any pink colour produced by the sample shall not exceed that produced by the standard selenium solution (A-7.1.2).

Bureau of Indian Standards

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards : Monthly Additions'.

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Amendments Issued Since Publication

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